

Model Guidelines for the Recommendation of Marijuana in Patient Care

Report of the FSMB Workgroup on Marijuana and Medical Regulation

*Adopted as policy by the Federation of State Medical Boards
April 2016*

INTRODUCTION

Over the past two decades, the attitudes and laws in the United States have become more tolerant towards marijuana, with the proportion of adults using the substance doubling between 2001 and 2013. Due to the increasing number of state governments authorizing the use of marijuana and marijuana infused product for “medicinal purposes,” state medical and osteopathic boards now have the added responsibility for the regulatory oversight of physicians choosing to incorporate the recommendation of marijuana in patient care and management.

The Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on Marijuana and Medical Regulation to develop model policy guidelines regarding the recommendation of marijuana in patient care, including conditions, diseases, or indications for which marijuana may be recommended. The Workgroup was further tasked with the development of a position statement or white paper regarding the regulation of licensees who use marijuana, which will be addressed in a separate document.

In order to accomplish this charge, the Workgroup reviewed existing laws and medical and osteopathic board rules, regulations and policies related to marijuana; reviewed current literature and policies related to the incorporation of marijuana by health care professionals in their professional practice and related research; and reviewed cases of board disciplinary actions related to the recommendation of marijuana in patient care and/or use and abuse of marijuana by licensees.

This policy document is intended as a resource to state medical boards in regulating physicians and physician assistants (or other licensees regulated by the board) with a full and unrestricted license participating in marijuana programs and may also be valuable in educating licensees as to the board’s expectations when recommending marijuana to a patient for a particular medical condition. The guidelines should in no way be construed as encouraging or endorsing physicians to recommend marijuana as a part of patient care.

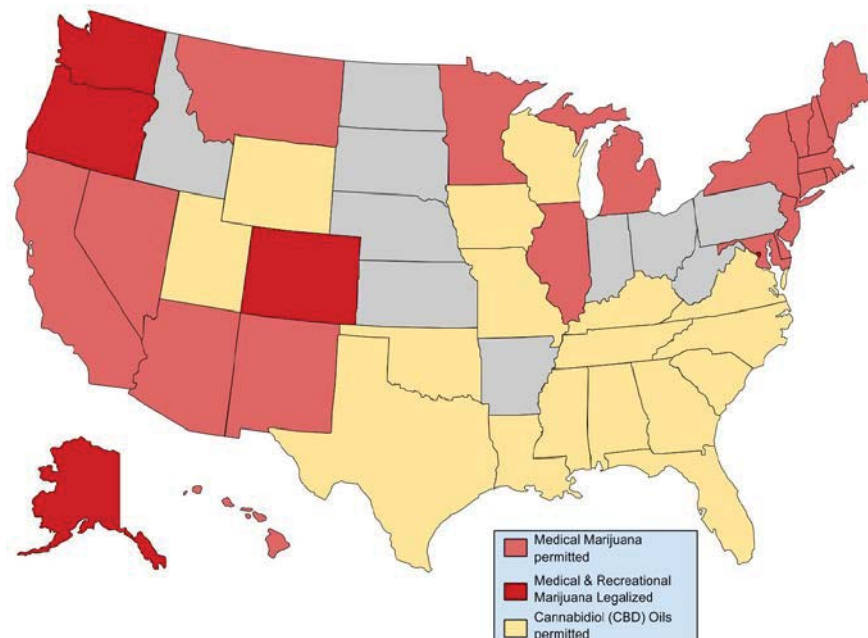
In developing the model guidelines that follow, the Workgroup conducted a comprehensive review of marijuana statutes, rules, and state medical board policies currently enacted across the country, and considered research reports, peer-reviewed articles, and policy statements regarding the recommendation of marijuana in patient care. In addition, a survey of FSMB member boards was conducted to determine which issues related to marijuana and medical regulation are of high priority to state boards. Fifty-one out of 70 state boards completed the survey, yielding a 72.9% response rate. Many boards reported several issues being most important to their board about

marijuana and medical regulation, including guidance on handling recreational use by physicians (31.4%), guidance on handling marijuana for medical use by physicians (47.1%), and model guidelines for recommending marijuana for medical purposes to patients (49.0%).

Section One. Background.

Marijuana has been suggested for alleviating symptoms of a range of debilitating medical conditions, such as cancer, HIV/AIDS, multiple sclerosis, Alzheimer’s Disease, post-traumatic stress disorder (PTSD), epilepsy, Crohn’s Disease, and glaucoma, as well as an alternative to narcotic painkillers. Accordingly, marijuana use in patient care has increased in popularity nationwide since 1996 when California voters passed Proposition 215, making it the first state to allow marijuana to be recommended in patient care. Since then, 22 other states, in addition to the District of Columbia and Guam, have enacted laws or passed ballot initiatives establishing comprehensive “medical marijuana programs,” authorizing marijuana for medical purposes.¹ Moreover, 17 states have enacted laws to permit limited use of cannabidiol (CBD) oils for the treatment of specific illnesses and symptoms.² See Figure 1.

Figure 1: State Map of Marijuana and Cannabidiol Oils Laws



¹ The states and territories that have enacted comprehensive marijuana programs are: Alaska (AS 17.37.070), Arizona (A.R.S. § 36-2801), California (Cal. Health & Safety Code § 11362.7 et seq.), Colorado (Colo. Rev. Stat. § 25-1.5-106), Connecticut (Conn. Gen. Stat. §420f-21a-408), Delaware (Del. Code tit. 16 § 4901A et seq.), District of Columbia (D.C. Code § 7-1671.01 et seq.), Guam (10 Guam Code Ann. § 122501 et seq.), Hawaii (Haw. Rev. Stat. § 329-121), Illinois (410 Ill. Comp. Stat. § 130/10), Maine (Me. Stat. tit. 22, § 2422 et seq.), Maryland (Md. Code, Health Gen. § 13-3301 et seq.), Massachusetts (105 Code of Mass. Regs. 725.000), Michigan (Mich. Comp. Laws § 333.26423), Minnesota (Minn. Stat. § 152.21 et seq.), Montana (Mont. Code Ann. § 50-46-301 et seq.), Nevada (NRS 453A), New Hampshire RSA 126-X), New Jersey (N.J.S.A. C.24:6I-3), New Mexico (N.M. Stat. § 26-2B-1 et seq.), New York (NY Pub Health Law § 3360), Oregon (Or. Rev. Stat. § 475.300 et seq.), Rhode Island (R.I. Gen. Laws § 21-28.6-3), Vermont (18 V.S.A. § 4472 et seq.), and Washington (RCS 69.51A).
Recreational Marijuana Ballot Initiatives: Alaska (2014); Colorado (2012); District of Columbia (2014); Oregon (2014); Washington (2012).

² The states that have enacted laws permitting limited use of cannabidiol oils are: Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.

Although states have enacted laws permitting the use of both medical and recreational marijuana, the prescribing of marijuana remains illegal under federal law, as marijuana has not been subject to the U.S. Food and Drug Administration's evaluation and approval process. Marijuana is classified in federal law as a Schedule 1 substance under the Controlled Substance Act.³ As a Schedule 1 substance, the federal government classifies marijuana as a substance with high potential for dependency or addiction, with no accepted medical use. Federal law prohibits knowingly or intentionally distributing, dispensing, or possessing marijuana.⁴ Additionally, a person who aids and abets another in violating federal law or engages in a conspiracy to purchase, cultivate, or possess marijuana may be punished to the same extent as the individual who commits the crime.⁵

Providers and state regulators should continue to monitor usage and adverse effects of marijuana. See Figure 2. Based on the increasing number of states permitting the recommendation of marijuana in patient care, the U.S. Department of Justice updated its marijuana enforcement policy in August 2013. The updated policy reiterates marijuana's classification as an illegal substance under federal law, but advises states and local governments that authorize marijuana-related conduct to implement strong and effective regulatory and enforcement systems to address any threat state laws could pose to public safety, public health, and other interests. Should these state efforts be insufficient, the federal government may seek to challenge the regulatory structure itself and bring forward individual enforcement actions.⁶

The Guidelines that follow are designed to communicate to state medical board licensees that if marijuana is recommended, these recommendations should be consistent with accepted professional and ethical practices.

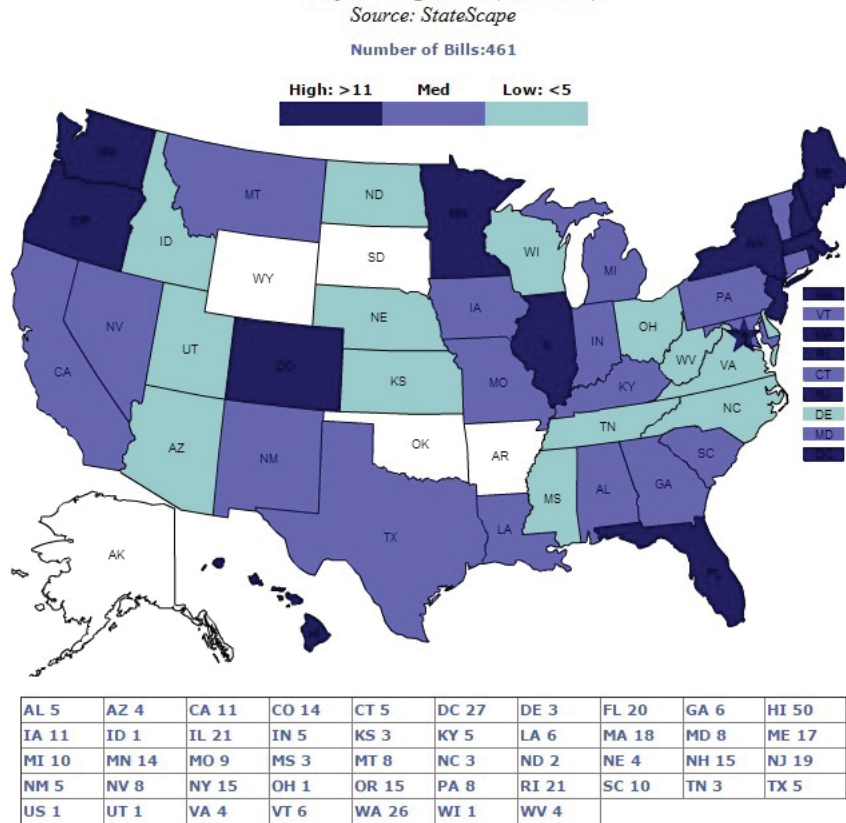
³ 21 U.S.C. §812.

⁴ 21 U.S.C. §841-44.

⁵ 18 U.S.C. §2; 21 U.S.C. §846.

⁶ James M. Cole, "Guidance Regarding Marijuana Enforcement [Memorandum]," Washington, DC: Department of Justice. (August 19, 2013).

Figure 2: Marijuana Legislation (2013-2015)



Section Two. Definitions.

For the purposes of these guidelines, the following definitions apply:

“Marijuana” means the leaves, stems, flowers, and seeds of all species of the plant genus cannabis, whether growing or not. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil or cake or sterilized seed of the plant which is incapable of germination.

“Medical Marijuana Program” is the term used in some state statutes, rules, and regulations that provide for the medical use, cultivation and dispensing of marijuana for medical purposes, which may or may not include specific medical conditions for which a physician (or other licensed health care provider) may issue a recommendation, attestation, or authorization for a patient to obtain and use marijuana.

“Cannabidiol (CBD) Oil” means processed cannabis plant extract, oil, or resin that contains a high percentage of cannabidiol, but a low percentage of tetrahydrocannabinol.

“Tetrahydrocannabinol (THC)” means the primary psychoactive compound in cannabis, delta-9-tetrahydrocannabinol (THC), which is a partial agonist at cannabinoid receptors in the body.

Section Three. Guidelines.

The [Name of Board] has adopted the following guidelines for the recommendation of marijuana in patient care:

Physician-Patient Relationship: The health and well-being of patients depends upon a collaborative effort between the physician and the patient. The relationship between a patient and a physician is complex and based on the mutual understanding of the shared responsibility for the patient’s health care. The physician-patient relationship is fundamental to the provision of acceptable medical care. Therefore, physicians must have documented that an appropriate physician-patient relationship has been established,⁷ prior to providing a recommendation, attestation, or authorization for marijuana to the patient. Consistent with the prevailing standard of care, physicians should not recommend, attest, or otherwise authorize marijuana for themselves or family member.

Patient Evaluation: A documented in-person medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient must be obtained before a decision is made as to whether to recommend marijuana for medical use. At minimum, the evaluation should include the patient’s history of present illness, social history, past medical and surgical history, alcohol and substance use history, family history with emphasis on addiction or mental illness/ psychotic disorders, physical exam, documentation of therapies with inadequate response, and diagnosis requiring the marijuana recommendation.

Informed and Shared Decision Making: The decision to recommend marijuana should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the use of marijuana with the patient. Patients should be advised of the variability and lack of standardization of marijuana preparations and the effect of marijuana. Patients should be reminded not to drive or operate heavy machinery while under the influence of marijuana. If the patient is a minor or without decision-making capacity, the physician should ensure that the patient’s parent, guardian or surrogate is involved in the treatment plan and consents to the patient’s use of marijuana.

⁷ The health and well-being of patients depends upon a collaborative effort between the physician and patient. The relationship between the physician and patient is complex and is based on the mutual understanding of the shared responsibility for the patient’s health care. Although the Board recognizes that it may be difficult in some circumstances to precisely define the beginning of the physician-patient relationship, particularly when the physician and patient are in separate locations, it tends to begin when an individual with a health-related matter seeks assistance from a physician who may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an encounter in person between the physician (or other appropriately supervised health care practitioner) and patient. FSMB *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine* (HOD 2014).

Treatment Agreement: A health care professional should document a written treatment plan that includes:

- Review of other measures attempted to ease the suffering caused by the terminal or debilitating medical condition that do not involve the recommendation of marijuana.
- Advice about other options for managing the terminal or debilitating medical condition.
- Determination that the patient with a terminal or debilitating medical condition may benefit from the recommendation of marijuana.
- Advice about the potential risks of the medical use of marijuana to include:
 - The variability of quality and concentration of marijuana;
 - The risk of cannabis use disorder;
 - Exacerbation of psychotic disorders and adverse cognitive effects for children and young adults;
 - Adverse events, exacerbation of psychotic disorder, adverse cognitive effects for children and young adults, and other risks, including falls or fractures;
 - Use of marijuana during pregnancy or breast feeding;
 - The need to safeguard all marijuana and marijuana-infused products from children and pets or domestic animals; and
 - The need to notify the patient that the marijuana is for the patient's use only and the marijuana should not be donated or otherwise supplied to another individual.
- Additional diagnostic evaluations or other planned treatments.
- A specific duration for the marijuana authorization for a period no longer than twelve months.
- A specific ongoing treatment plan as medically appropriate.

Qualifying Conditions: At this time, there is a paucity of evidence for the efficacy of marijuana in treating certain medical conditions. Recommending marijuana for certain medical conditions is at the professional discretion of the physician. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with current standards of practice and in compliance with state laws, rules and regulations which specify qualifying conditions for which a patient may qualify for marijuana.

Ongoing Monitoring and Adapting the Treatment Plan: Where available, the physician recommending marijuana should register with the appropriate oversight agency and provide the registry with information each time a recommendation, attestation, authorization, or reauthorization is issued [see Appendix 1]. Where available, the physician recommending marijuana should check the state Prescription Drug Monitoring Program (PDMP) each time a recommendation, attestation, authorization, or reauthorization is issued.

The physician should regularly assess the patient's response to the use of marijuana and overall health and level of function. This assessment should include the efficacy of the treatment to the patient, the goals of the treatment, and the progress of those goals.

Consultation and Referral: A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment. The physician should seek a consultation with, or refer the patient to, a pain management, psychiatric, addiction or mental health specialist, as needed.

Medical Records: The physician should keep accurate and complete medical records. Information that should appear in the medical record includes, but is not necessarily limited to the following:

- The patient's medical history, including a review of prior medical records as appropriate;
- Results of the physical examination, patient evaluation, diagnostic, therapeutic, and laboratory results;
- Other treatments and prescribed medications;
- Authorization, attestation or recommendation for marijuana, to include date, expiration, and any additional information required by state statute;
- Instructions to the patient, including discussions of risks and benefits, side effects and variable effects;
- Results of ongoing assessment and monitoring of patient's response to the use of marijuana;
- A copy of the signed Treatment Agreement, including instructions on safekeeping and instructions on not sharing.

Physician Conflicts of Interest: A physician who recommends marijuana should not have a professional office located at a dispensary or cultivation center or receive financial compensation from or hold a financial interest in a dispensary or cultivation center. Nor should the physician be a director, officer, member, incorporator, agent, employee, or retailer of a dispensary or cultivation center.

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Appendix 1: Registration

Many states that permit the recommendation of marijuana to patients for the treatment of serious medical conditions have laws establishing a registry to track and monitor the utilization of marijuana in patient care.⁸

In these states, physicians recommending marijuana to patients for the treatment of conditions are required to register with the regulatory agency overseeing the marijuana program, and must provide the registry with information each time a recommendation is issued.

The state's registry is required by law to regularly perform analyses of the number of recommendations issued. With the statistical review of physician recommendations, the regulating agency periodically determines whether a physician should be referred to the state medical or osteopathic board for review and possible sanction.

The following are common factors oversight agencies rely on in referring physicians to the state board for possible abuse of marijuana recommendations:

1. Physician caseload as determined by the number of patients for whom marijuana is recommended. A high caseload is calculated as 3,521 or more patient recommendations in one year for a general practitioner. This reflects the recommendation of patients equal to or greater than the national average of patient visits per year for a generalist physician as reported by the Centers for Disease Control and Prevention (Co. Registry Policy # 2014-04_001);
2. The plant and ounce recommendations by the physician. Physicians recommending an amount of marijuana above the standard set within a state's statutes will be referred to the state medical board for review;
3. Age demographics of the patient caseload. According to the CDC, older adults have a significantly higher prevalence of chronic conditions than younger adults. Physicians for whom more than one-third of the patient caseload is under the age of 30 may be recommended for referral; and
4. Other circumstances determined by the overseeing agency. The oversight agency may also refer physicians to the state medical board if there is evidence of potential violation of the constitution, statutes, state medical board regulations or any violation of the Medical Practice Act.

If evidence supports a referral, the overseeing agency will issue a formal referral to the state medical board with the physician's identifying information, the reason for the referral, and any statistical data supporting the referral. Once the referral is received, the state medical board typically reviews the documentation and conducts an investigation as deemed appropriate.

⁸ See e.g. Colorado Medical Marijuana Registry; See e.g. Minnesota Medical Cannabis Registry

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**Comparison of Federation of State Medical Boards (FSMB) Guidelines to
Medical Board of California (MBC) Statement for the Recommendation of Marijuana in Patient Care**

FSMB (April 2016)		MBC (amended October 2014)
<u>Model Guidelines for the Recommendation of Marijuana in Patient Care</u>		<u>Marijuana for Medical Purposes (Statement)</u>
Physician-Patient Relationship	<p>The health and well-being of patients depends upon a collaborative effort between the physician and the patient. The relationship between a patient and a physician is complex and based on the mutual understanding of the shared responsibility for the patient's health care. The physician-patient relationship is fundamental to the provision of acceptable medical care. Therefore, physicians must have documented that an appropriate physician-patient relationship has been established, prior to providing a recommendation, attestation, or authorization for marijuana to the patient. Consistent with the prevailing standard of care, physicians should not recommend, attest, or otherwise authorize marijuana for themselves or family member.</p>	<p>Not currently addressed. (Note: B&P Code section 2525(a) states an individual who possesses a license in good standing to practice medicine or osteopathy issued by the Medical Board of California or the Osteopathic Medical Board of California shall not recommend medical cannabis to a patient, unless that person is the patient's attending physician, as defined by subdivision (a) of Section 11362.7 of the Health and Safety Code.)</p>
Patient Evaluation	<p>A documented in-person medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient must be obtained before a decision is made as to whether to recommend marijuana for medical use. At minimum, the evaluation should include the patient's history of present illness, social history, past medical and surgical history, alcohol and substance use history, family history with emphasis on addiction or mental illness/ psychotic disorders, physical exam, documentation of therapies with inadequate response, and diagnosis requiring the marijuana recommendation.</p>	<p>The initial examination for the condition for which marijuana is being recommended must be an appropriate prior examination and meet the standard of care. Telehealth, in compliance with Business and Professions Code section 2290.5, is a tool in the practice of medicine and does not change the standard of care. Accepted standards are the same as any reasonable and prudent physician would follow when recommending or approving any other medication including history and an appropriate prior examination of the patient.</p>

**Comparison of Federation of State Medical Boards (FSMB) Guidelines to
Medical Board of California (MBC) Statement for the Recommendation of Marijuana in Patient Care**

	FSMB (April 2016)	MBC (amended October 2014)
Informed and Shared Decision Making	<p>The decision to recommend marijuana should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the use of marijuana with the patient. Patients should be advised of the variability and lack of standardization of marijuana preparations and the effect of marijuana. Patients should be reminded not to drive or operate heavy machinery while under the influence of marijuana. If the patient is a minor or without decision-making capacity, the physician should ensure that the patient’s parent, guardian or surrogate is involved in the treatment plan and consents to the patient’s use of marijuana.</p>	<p>Provision of appropriate consent including discussion of side effects. If a physician recommends or approves the use of marijuana for a medical purpose for a minor, the parents or legal guardians must be fully informed of the risks and benefits of such use and must consent to that use.</p>
Treatment Agreement	<p>A health care professional should document a written treatment plan that includes:</p> <ul style="list-style-type: none"> • Review of other measures attempted to ease the suffering caused by the terminal or debilitating medical condition that do not involve the recommendation of marijuana. • Advice about other options for managing the terminal or debilitating medical condition. • Determination that the patient with a terminal or debilitating medical condition may benefit from the recommendation of marijuana. • Advice about the potential risks of the medical use of marijuana to include: <ol style="list-style-type: none"> 1. The variability of quality and concentration of marijuana; 2. The risk of cannabis use disorder; 3. Exacerbation of psychotic disorders and adverse cognitive effects for children and young adults; 4. Adverse events, exacerbation of psychotic disorder, adverse cognitive effects for children and young adults, and other risks, including falls or fractures; 5. Use of marijuana during pregnancy or breast feeding; 6. The need to safeguard all marijuana and marijuana-infused products from children and pets or domestic animals; and 7. The need to notify the patient that the marijuana is for the patient’s use only and the marijuana should not be donated or otherwise supplied to another individual. • Additional diagnostic evaluations or other planned treatments. • A specific duration for the marijuana authorization for a period no longer than twelve months. • A specific ongoing treatment plan as medically appropriate. 	<p>Development of a treatment plan with objectives. The physician should determine that marijuana use is not masking an acute or treatable progressive condition, or that such use will lead to a worsening of the patient’s condition.</p>

**Comparison of Federation of State Medical Boards (FSMB) Guidelines to
Medical Board of California (MBC) Statement for the Recommendation of Marijuana in Patient Care**

	FSMB (April 2016)	MBC (amended October 2014)
Qualifying Conditions	At this time, there is a paucity of evidence for the efficacy of marijuana in treating certain medical conditions. Recommending marijuana for certain medical conditions is at the professional discretion of the physician. The indication, appropriateness, and safety of the recommendation should be evaluated in accordance with current standards of practice and in compliance with state laws, rules and regulations which specify qualifying conditions for which a patient may qualify for marijuana.	A patient need not have failed on all standard medications in order for a physician to recommend or approve the use of marijuana for medical purposes. The Compassionate Use Act of 1996 names certain medical conditions for which marijuana may be useful, although physicians are not limited in their recommendations to those specific conditions. In all cases, the physician should base his/her determination on the results of clinical trials, if available, medical literature and reports, or on experience of that physician or other physicians, or on credible patient reports. In all cases, the physician must determine that the risk/benefit ratio of marijuana is as good, or better, than other treatment options that could be used for that individual patient.
Ongoing Monitoring and Adapting the Treatment Plan	Where available, the physician recommending marijuana should register with the appropriate oversight agency and provide the registry with information each time a recommendation, attestation, authorization, or reauthorization is issued. Where available, the physician recommending marijuana should check the state Prescription Drug Monitoring Program (PDMP) each time a recommendation, attestation, authorization, or reauthorization is issued. The physician should regularly assess the patient's response to the use of marijuana and overall health and level of function. This assessment should include the efficacy of the treatment to the patient, the goals of the treatment, and the progress of those goals.	Periodic review of the treatment's efficacy. Recommendations should be limited to the time necessary to appropriately monitor the patient. Periodic reviews should occur and be documented at least annually or more frequently as warranted.
Consultation and Referral	A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment. The physician should seek a consultation with, or refer the patient to, a pain management, psychiatric, addiction or mental health specialist, as needed.	Consultation, as necessary.

**Comparison of Federation of State Medical Boards (FSMB) Guidelines to
Medical Board of California (MBC) Statement for the Recommendation of Marijuana in Patient Care**

	FSMB (April 2016)	MBC (amended October 2014)
Medical Records	<p>The physician should keep accurate and complete medical records. Information that should appear in the medical record includes, but is not necessarily limited to the following: • The patient’s medical history, including a review of prior medical records as appropriate; • Results of the physical examination, patient evaluation, diagnostic, therapeutic, and laboratory results; • Other treatments and prescribed medications; • Authorization, attestation or recommendation for marijuana, to include date, expiration, and any additional information required by state statute; • Instructions to the patient, including discussions of risks and benefits, side effects and variable effects; • Results of ongoing assessment and monitoring of patient’s response to the use of marijuana; • A copy of the signed Treatment Agreement, including instructions on safekeeping and instructions on not sharing.</p>	<p>Proper record keeping and maintenance thereof that supports the decision to recommend the use of marijuana for medical purposes.</p>
Physician Conflicts of Interest	<p>A physician who recommends marijuana should not have a professional office located at a dispensary or cultivation center or receive financial compensation from or hold a financial interest in a dispensary or cultivation center. Nor should the physician be a director, officer, member, incorporator, agent, employee, or retailer of a dispensary or cultivation center.</p>	<p>Not currently addressed. (Note: Several new laws have since been enacted on this subject; including, B&P Code section 2525(a), which states it is unlawful for a physician and surgeon who recommends cannabis to a patient for a medical purpose to accept, solicit, or offer any form of remuneration from or to a facility issued a state license pursuant to Chapter 3.5 (commencing with Section 19300) of Division 8, if the physician and surgeon or his or her immediate family have a financial interest in that facility. As well as, B&P Code section 2525.4, which states it is unprofessional conduct for any attending physician recommending medical cannabis to be employed by, or enter into any other agreement with, any person or entity dispensing medical cannabis.)</p>

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Non-primary Treating Physician	Not applicable. See "Physician-Patient Relationship".	<p>A physician who is not the primary treating physician may still recommend marijuana for a patient's symptoms. However, it is incumbent upon that physician to consult with the patient's primary treating physician or obtain the appropriate patient records to confirm the patient's underlying diagnosis and prior treatment history.</p> <p>(Note: B&P Code section 2525.2 states an individual who possesses a license in good standing to practice medicine or osteopathy issued by the Medical Board of California or the Osteopathic Medical Board of California shall not recommend medical cannabis to a patient, unless that person is the patient's attending physician, as defined by subdivision (a) of Section 11362.7 of the Health and Safety Code.)</p>